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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,711	04/22/2002	Kazumi Iijima	KKH-013	8628

7590 01/26/2006

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EXAMINER	
DESANTO, MATTHEW F	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,711	IIJIMA ET AL.	
	Examiner	Art Unit	
	Matthew F. DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-10* is/are rejected.

7)☒ Claim(s) 7-10 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 7-10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 7-10 are drawn to cancelled claims.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 7-10 are dependent are canceled claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimber et al. (USPN 6,068,614).

Kimber et al. discloses a plunger with a screw portion; a pair of ring members, and a plurality of vane members, as well as a flange portion and one or two gripping ring members, (Figure 7 and entire reference), but fails to specifically disclose the rings members being located in a region less than ¼ the total length of the plunger

At the time of the invention it would have been obvious to one of ordinary skill in the art to change the size and dimensions of the syringe since this is an obvious matter of design choice. The applicant also fails to provide any criticality and/or unexpected results, therefore it appears that the invention would perform equally as well with any size or dimension, which is what is being taught by the prior art. The examiner makes the assumption that the area in which the rings are disposed would be ¼ of the length of the plunger by looking at the figures, but decided that this would be an obvious modification if that determination could not be met. The examiner also determines that the inside diameter of the ring members would be the equal to the inner diameter of the barrel by looking at figure 6 and 7 and if the applicant disagrees this also would be an obvious modification since all plungers are intended to inject medicated and would need to form a seal between the plunger and the barrel, therefore the ring members would form that seal as well as the gasket.

7. Claims 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Hirschman et al. (USPN 6042565).

Hirschman et al. discloses a plunger with a screw portion; a pair of ring members, and a plurality of vane members, as well as a flange portion and one or two gripping ring members (Figures 1, 2A, 2C, 2D, 4A, and entire reference), but fails to

disclose the rings members being disposed apart from each other by .5 mm or more and the interval between the first ring member and the second rind member is less than a distance between a rear surface of the gasket.

At the time of the invention it would have been obvious to one of ordinary skill in the art to change the size and dimensions of the syringe since this is an obvious matter of design choice. The applicant also fails to provide any criticality and/or unexpected results, therefore it appears that the invention would perform equally as well with any size or dimension, which is what is being taught by the prior art. The examiner would like to mention that the "screw" portion of Hirschman et al. is being interpreted as reference number 40, since this portion has a characteristic like a screw, with regards to a cylinder portion with a thread member being radially disposed. The thread member is where the gasket will become threaded to the plunger, which can be seen in figure 3D.

Response to Arguments

8. Applicant's arguments with respect to claims 6-10 have been considered but are not persuasive.

9. Applicant's arguments with regards to Minkus et al. and Shanley et al. are persuasive and therefore, the rejections drawn to them are withdrawn.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Matthew DeSanto
Art Unit 3763
January 23, 2006

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